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EPPERSON, JON D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,340	HUANG, CHIN-SHIOU	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27 and 58-63* is/are pending in the application.

4a) Of the above claim(s) *9,10,12 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11,13-25,27 and 58-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/6/06; 4/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. The Response filed July 18, 2007 is acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Status of the Claims

3. Claims 1-57 were pending. Applicants added claims 58-63 and canceled claims 28-57. In addition, Applicants amended claim 1, 4, 6, 27. Therefore, claims 1-27 and 58-63 are currently pending. Claims 9, 10, 12, and 26 are drawn to non-elected species and/or inventions and thus these claims remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), there being no allowable generic claim. Please note that claim 12 was inadvertently omitted from this list in the previous office action but it is also withdrawn as it depends from another withdrawn claim (i.e., claim 10).

4. Therefore, claims 1-8, 11, 13-25, 27 and 58-63 are examined in this action.

Withdrawn Objections/Rejections

5. The objection to the specification is withdrawn in view of Applicants' amendments thereto. The 35 U.S.C. § 112, second paragraph rejection denoted "A" is withdrawn in view of Applicants' amendments to the claims removing the word "substantial." The 35 U.S.C. § 112,

second paragraph rejection denoted "B" is withdrawn in view of Applicants' amendments which further define heat sensitive as a compound "capable of undergoing a change of physical state by heat." The 35 U.S.C. § 112, second paragraph rejection denoted "C" is withdrawn in view of Applicants' amendments to claim 6. The double patenting rejection is withdrawn in view of Applicants' submission of a terminal disclaimer over the '573 patent. All 35 U.S.C. § 102 rejections are withdrawn in view of Applicants' amendments to claims 1 and 27. All other rejections are maintained and the arguments are addressed below.

Outstanding Objections and/or Rejections

Claim Rejections - 35 USC § 112, first paragraph

6. Claims 1-8, 11, 13-25 and 27 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 USC 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4 pages 1099-1111, Friday January 5, 2001. This is a written description rejection.

Applicants' claims are directed to a broad genus of surface imprint compositions comprising a matrix material defining imprint cavities of a template molecule wherein the imprint cavities are formed by contacting with a conjugate molecule the conjugate molecule includes a tail moiety and a template moiety constituting the template molecule and wherein a fraction of the imprint cavities are oriented (e.g., see independent claims 1

and 27). Thus, Applicants' claims encompass virtually an infinite number of compositions because no structural limitations are set forth for the matrix material, cavity, template, conjugate molecule, tail moiety, template moiety, etc. (e.g., see specification, section 5.4, "Virtually any type of macromolecule can be captured, isolated, detected, analyzed and/or quantified using the methods and compositions of the invention"; see also page 5, last two paragraph wherein the "tail moiety" merely needs to be "complementary" to the undefined template moiety in terms of hydrophobicity but is not otherwise limited to any particular structure; see also pages 25 and 26 wherein some non-limiting examples are shown with a wide range of structures). That is, the specification and claims do not place any limit on the number of atoms, the types of atoms, or the manner in which said atoms might be connected to form claimed composition. The claimed composition could be constructed using any element in the periodic table combined in virtually an infinite number of combinations. Furthermore, the dependent claims likewise fail to limit one or more of these claimed elements. For example, dependent claim 2 fails to limit the target and the cavity and still reads on virtually an infinite number of polymer matrices.

In contrast, Applicants' specification disclose only one working example of a polyacrylamide composition that is used to define cavities for a cytochrome c protein target using a palmitic acid tail molecule (e.g., see Examples 1 and 4 wherein the LKKATNE of the c-terminus is used to prepare the imprint; see also Examples 2, 3, 5, and 6 outlying various methods of use for this system). Although the specification sets forth a laundry list of other species (e.g., see claim 3 disclosing a laundry list or polymer

materials), there is no evidence that any of these materials was actually made or tested.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the claimed invention (e.g., see *In re Edwards*, 568 F.2d 1349, 1351-52, 196 USPQ 465, 467 (CCPA 1978); see also see also *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111 (CAFC 1991)). The "written description" requirement may be satisfied by using "such descriptive means as words, structures, figures, diagrams formulas, etc., that fully set forth the claimed invention" (e.g., see *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966). In addition, when there is *substantial variation within the genus*, one must describe a sufficient variety of species to reflect the variation within the genus (e.g., see MPEP § 2163.05). Here, Applicant's one example (e.g., polyacrylamide imprinted with a cytochrome c peptide target with palmitic tail) does not adequately represent the variation within the genus because Applicants are claiming virtually an infinite number of compositions that do not possess any common structural attributes. For example, Cormack et al. state, "much more research is also required to extend the size range of templates that can be routinely imprinted. At present only small molecules ... can be imprinted with any great confidence" (e.g., see Cormack et al., page 122, column 2, paragraph 3) (3/13/06 IDS, C1). Thus, a person of skill in the art would not conclude that Applicants were in possession of surface imprint compositions containing cavities for larger template molecules, especially in light of the fact that their only disclosed working example is drawn to a small peptide (e.g., LKKATNE). Furthermore, Cormack et al. state, "a much better understanding of the imprinting process at the molecular level is

necessary ... [to develop] new functional monomers, cross-linkers and polymerization procedures" (e.g., see Cormack et al., page 122, column 1, paragraph 1) and, as a result, a person of skill in the art would not conclude that Applicants were in possession of every conceivable monomer, cross-linker and polymerization process that would otherwise be necessary to produce the infinite number of currently claimed compositions developed using every element in the periodic table combined in any manner.

The CAFC has also stated that a "written description on an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." (e.g., see *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993)). Here, Applicants have failed to provide a definition, structure, formula or chemical name for any of the compositions. For example, claim 1 sets forth the composition is purely functional terms (e.g., matrix material that has the ability to define a cavity of a molecule that hast the ability to function as a template).

Thus, applicants have not demonstrated in "full, clear, concise, and exact terms" that they are in possession of the claimed invention. Furthermore, the general knowledge and level of skill in the art do not supplement the omitted description because no known structure/function relationship and/or chemical properties exists that could otherwise be used to show possession of the claimed compositions. In addition, no generally accepted method for producing these unknown compositions has been set forth. It is well settled that claiming only a result (e.g., matrix materials having the ability to imprint all target

molecules) fails to satisfy the constitutional requisite of promoting the progress of science and the useful arts since this seeks to monopolize all possible ways to achieve a given result, far beyond those means actually discovered or contemplated by the inventor (e.g., a single acrylamide matrix imprinted with an LKKATNE template peptide), so that others would have no incentive thereafter to explore a field already fully dominated. *O'Reilly v. Morse*, 15 How. 62, *In re Fuetterer*, 50 CCPA 1453, 1963 C.D. 620, 795 O.G. 783, 319 F.2d 259, 138 USPQ 217 ; *Siegel v. Watson*, 105 U.S. Appl. D.C. 344, 1959 C.D. 107, 742 O.G 863, 267 F.2d 621, 121 USPQ 119.

7. Claims 1-8, 11, 13-25 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polyacrylamide surface imprint of a cytochrome c peptide, does not reasonably provide enablement for a composition created from any material that can imprint any target. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". Some of these factors may include, but are not limited to:

(1) the breadth of the claims;
(2) the nature of the invention;
(3) the state of the prior art;
(4) the level of one of ordinary skill;
(5) the level of predictability in the art;

(6) the amount of direction provided by the inventor;
(7) the existence of working examples; and
(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: Applicants' claims are directed to a broad genus of surface imprint compositions comprising a matrix material defining imprint cavities of a template molecule wherein the imprint cavities are formed by contacting with a conjugate molecule the conjugate molecule includes a tail moiety and a template moiety constituting the template molecule and wherein a fraction of the imprint cavities are oriented (e.g., see claims 1 and 27). Thus, Applicants' claims encompass virtually an infinite number of compositions because no structural limitations are set forth for the matrix material, cavity or template (e.g., see specification, section 5.4, "Virtually any type of macromolecule can be captured, isolated, detected, analyzed and/or quantified using the methods and compositions of the invention"; see also 35 U.S.C. 112, second paragraph rejection (denoted c) below wherein the metes and bound of the claimed template molecules cannot be determined). That is, the specification and claims do not place any limit on the number of atoms, the types of atoms, or the manner in which said atoms might be connected to form claimed composition. Furthermore, the dependent claims likewise fail to limit one or more of these claimed elements. For example, dependent claim 2 fails to limit the target and the cavity and still reads on virtually an infinite number of polymer matrices. Consequently, the nature of the invention cannot be fully determined because the invention has not been defined with particularity.

(3 and 5) The state of the prior art and the level of predictability in the art: The level of predictability in the art is low or absent. For example, Cormack et al. state, "much more research is also required to extend the size range of templates that can be routinely imprinted. At present only small molecules ... can be imprinted with any great confidence" (e.g., see Cormack et al., "Molecular imprinting: recent developments and the road ahead" Reactive & Functional Polymers 41, 1999, 115-124, especially page 122, column 2, paragraph 3) (3/13/06 IDS, C1). Furthermore, Cormack et al. state, "a much better understanding of the imprinting process at the molecular level is necessary ... [to develop] new functional monomers, cross-linkers and polymerization procedures" (e.g., see Cormack et al., page 122, column 1, paragraphs 1 and 2; see also Conclusions). In addition, although Cormack et al. state that the field is rapidly developing, they acknowledge that commercial products based on imprinting do not yet exist (e.g., see Cormack et al., page 123, column 1, paragraph 1), which indicates that the field is young and still developing as opposed to a more mature art.

(4) The level of one of ordinary skill: The level of skill required would be high, most likely at the Ph.D. level.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants disclose only one working example of a polyacrylamide composition that is used to define cavities for a cytochrome c protein target (e.g., see Examples 1 and 4 wherein the LKKATNE of the c-terminus is used to prepare the imprint; see also Examples 2, 3, 5, and 6 outlying various methods of use for this system). Although the specification sets forth a laundry list of other species (e.g., see

claim 3 disclosing a laundry list or polymer materials), there is no evidence that any of these materials was actually made or tested.

(8) The quantity of experimentation needed to make or use the invention base on the content of the disclosure: As a result of the broad and unpredictable nature of the invention and the lack of specific guidance from the specification, the Examiner contends that the quantity of experimentation needed to make and or use the invention would be great. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 * n.23 (Fed. Cir. 19991). In this case, Applicants have not provided enough examples and/or species to teach this large, unpredictable genus. Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

Response

8. Applicant's arguments directed to the above written description rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

Applicants argue that their new claimed limitation (i.e., "wherein the imprint cavities are formed by contacting with a conjugate molecule, the conjugate molecule includes a tail moiety and a template moiety constituting the template molecule") and cite several prophetic sections of the specification in support of this position (e.g., see 7/18/07 Response, pages 10 and 11).

Factors to be considered in determining whether there is sufficient evidence of possession include "**[1]** the level of skill and knowledge in the art, **[2]** partial structure, **[3]** physical and/or chemical properties, **[4]** functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the **[5]** method of making the claimed invention" (e.g., see MPEP § 2163). Here, the level of skill and knowledge in the art is low as exemplified by Cormack et al. stating as noted in the rejection, "a much better understanding of the imprinting process at the molecular level is necessary ... [to develop] new functional monomers, cross-linkers and polymerization procedures" (e.g., see Cormack et al., page 122, column 1, paragraphs 1 and 2; see also Conclusions). In addition, although Cormack et al. state that commercial products based on imprinting do not yet exist (e.g., see Cormack et al., page 123, column 1, paragraph 1). In addition, Cormack states with respect to larger template molecules, "much more research is also required to extend the size range of templates that can be routinely imprinted. At present only small molecules ... can be imprinted with any great confidence" (e.g., see Cormack et al., "Molecular imprinting: recent developments and the road ahead" Reactive & Functional Polymers 41, 1999, 115-124, especially page 122, column 2, paragraph 3). Thus, it is clear that the level of skill and knowledge in the art are low, a point that has not been contested by Applicants. Thus, Applicants have conceded **[1]** the level of skill and knowledge in the art as noted above. In addition, the Examiner has noted that the claims

encompass such a wide range of structurally diverse compositions that no partial structure or correlation between structure and function is possible. Again, Applicants have not contested the fact that their claimed scope reads on anything less than an infinite number of structurally unrelated compositions. Consequently **[2]-[4]** have also been conceded by Applicants. Finally, Applicants have not provided a method for making the infinite number of compositions that are currently claimed. Applicants have only provided for the use of polyacrylamide compositions that define cavities for a cytochrome c protein target using a palmitic acid tail molecule. Although it cannot be said that this point has been conceded, clearly this one species is not representative of the enormous claimed scope and, as result, point **[5]** also favors a finding for lack of written description.

Accordingly, the written description rejection cited above is hereby maintained.

New Rejections

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 1-8, 11, 13-25, 27 and 58-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. For **claims 1 and 27**, the phrase "wherein the imprint cavities are formed by

contacting with a conjugate molecule, the conjugate molecule includes a tail moiety and a template moiety constituting the template molecule" is vague and indefinite. For example, the claim does not specify what the conjugate molecule is contacted with? That is, it doesn't read wherein the imprint cavities are formed by contacting the matrix with the conjugate molecule ... ." Thus, the added limitation is nonsensical. Applicants are requested to clarify and/or correct. Therefore, claims 1, 27 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claims Rejections – 35 U.S.C. 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-3, 6-8, 11, 13-18, 20-22 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Arnold et al (U.S. Patent No. 5,310,648) (Date of Patent is **May 10, 1994**) as evidenced by NCBI. Horse Heart Myoglobin. Retrieved at http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=protein&id=118595772 on September 30, 2007).

For ***claims 1 and 27***, Arnold et al. (see entire document) disclose methods for using molecular imprint compositions that selectively bind predetermined molecules or biological particles (see Arnold et al, abstract), which anticipates the claimed invention. For example, Arnold et al. disclose a surface imprint composition comprising a matrix material defining imprint cavities of a template molecule wherein a substantial fraction of the imprint cavities are localized at or near the surface of the matrix material (e.g., see figure 1 showing a schematic diagram for preparing a molecular imprint of a protein by metal-chelating polymers wherein said protein interacts with the exposed surface of the polymer; see also figure 3a-c showing an imprinted matrix containing chelated copper attached to a lipid monomers after matrix has been polymerized to form a rigid structure and the template molecule has been removed; see also columns 7 and 8, especially column 8, lines 11-18, "The resulting fluid imprinted matrices have a large surface area accessible for protein binding [i.e., a substantial fraction are localized at the surface] and

can be used, for example, in chromatographic separations, in drug delivery, and for biosensors"; see also Examples 8-12; see especially Example 12, "Preparation of Fluid Imprinted Matrices"; see also 35 U.S.C. 112, second paragraph). In addition, Arnold et al. inherently disclose imprint cavities that are formed by contacting a conjugate molecule that includes a tail moiety and a template moiety. For example, NCBI discloses a "hydrophobic" tail (e.g., see page 4, wherein "mgls" is disclosed at positions 1-4) that would "complement" the hydrophilic portions of the rest of the sequence such as the "kkk" portion of the template at positions 78-80). Arnold et al. do not explicitly state that the cavities are "oriented", but the examiner contends that this would be an inherently disclosed by the reference because the use of polymerizable bi-layer, for example, would restrict the dimensions of the cavities accordingly (e.g., see figure 3; see also Example XII). Furthermore, the cavities are "oriented" via the copper interactions (e.g., see figure 2).

Alternatively, it is submitted that the product of Arnold et al. meet all of the structural limitations of the claimed product (see above) except for the product-by-process limitations (i.e., the recited method steps for forming the cavities) and thus would either anticipate or render obvious the claimed library. See MPEP § 2113, "'[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' *In re*

Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." Here, Applicants' claims are drawn to a composition (i.e., a product), but are defined by various method steps that produce said composition and, as a result, represent product-by-process claims. Thus, the process limitations do not appear to provide any patentable weight to the claimed invention in accordance with MPEP § 2113. One of ordinary skill would expect the product to be the same no matter how it was synthesized and/or prepared because the claim does not set forth what the conjugate molecule is contacted with (e.g., see 35 U.S.C. § 112, second paragraph). In addition, a medium (i.e., biphasic) is not set forth in the claimed process steps that might otherwise enable cavities formed from template-tail conjugates to be distinguished structurally from those formed from template molecules alone (e.g., see specification, section 5.3.1 wherein a "two-phase" system is required to impart "structural differences" using template-tail molecules). That is, unless a biphasic system is used in the process, a person of ordinary skill in the art would not expect a different cavity to be formed just because a "tail" has been added.

For ***claim 2***, Arnold et al. disclose polymers (e.g., see Example V, "Preparation of Imprinted Polymers"; see also Examples I and II).

For ***claim 3***, Arnold et al. disclose, for example, styrene (e.g., see Examples I and II, see also column 4, line 23; see also column 8, line 5; see also column 12, lines 40-41 wherein ethylene glycol dimethacrylate is disclosed; see also column 8, line 5 wherein methacrylate is disclosed).

For ***claims 6-8***, Arnold et al. disclose a template molecule corresponding to a portion of a macromolecule of interest such as a surface histidine residue of a protein that

is bound via a metal-ligand complex (e.g., see column 6, last paragraph; see especially columns 11 and 12, Example 5 wherein the imidazole ring "portion" of a protein amino acid side chain is disclosed; see also column 4, last full paragraph for a list of various template molecules). In addition, Arnold et al. disclose that the macromolecule can be bound at the imprint cavity (e.g., see figure 2). In addition, Arnold et al. disclose the use of the "terminal portion" of the amino acid side chains of the macromolecule such as the histidine imidazole ring (e.g., see figure 2). Furthermore, peptides containing histidine residues in the terminal portion of the chain would be immediately envisioned in view of the fact that histidine residues can occur anywhere in a peptide/protein and Arnold et al. disclose the use of all such peptides and proteins for this purpose. When, to arrive at the claimed subject matter, it is necessary to select portions of that subject matter from various sections of the reference disclosure and combine them (e.g., selecting values for variable substituents to interpolate into a generic structural formula to arrive at a specific compound or genus) anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. Ex parte A 17 USPQ2d 1716 (Bd. Pat. App. & Inter 1990); MPEP § 2131. Accordingly, a generic chemical formula will anticipate a species covered by the formula when the species can be "at once envisaged" from the formula. *In re Petering* 133 USPQ 275 (CCPA 1962); MPEP § 2131. See also 35 U.S.C. 112, second paragraph rejection for determining the metes and bounds of the term "corresponds" in claim 6.

For ***claims 11, 13-16***, Arnold et al. disclose the use of peptides and proteins of all shapes and sizes (e.g., see column 4, last full paragraph, "The template molecule can be

... amino acids ... larger molecules such as peptides ... proteins"). Consequently, use of peptides of various lengths and or the terminus of said peptides would be "immediately envisioned" in accordance with MPEP § 2131. When, to arrive at the claimed subject matter, it is necessary to select portions of that subject matter from various sections of the reference disclosure and combine them (e.g., selecting values for variable substituents to interpolate into a generic structural formula to arrive at a specific compound or genus) anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. Ex parte A 17 USPQ2d 1716 (Bd. Pat. App. & Inter 1990); MPEP § 2131. Accordingly, a generic chemical formula will anticipate a species covered by the formula when the species can be "at once envisaged" from the formula. *In re Petering* 133 USPQ 275 (CCPA 1962); MPEP § 2131.

For ***claims 17, 18, 20-22***, Arnold et al. disclose the use of two different template molecules to define two different cavities (e.g., see column 12 wherein the use of compounds 1 and 2 are disclosed; see more generally Example V and tables cited therein).

12. Claims 1, 2, 4, 6-8 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Zhao et al. (Zhao et al. "Soft lithographic methods for nano-fabrication" *J. Mater. Chem.* **1997**, *7(7)*, 1-69-1074).

For ***claims 1 and 27***, Zhao et al. disclose compositions for use in microcontact printing (e.g., see abstract; see also figure 1), which anticipates the claimed invention. For example, Zhao et al. disclose a surface imprint composition (e.g., see page 1070,

figure 1, top illustration wherein the composition represents the photoresist and Si substrate). In addition, Zhao et al. disclose that said surface imprint composition comprises a matrix material defining imprint cavities of a template molecule (e.g., see figure 1, second diagram from top wherein photoresist matrix material defines imprint cavities for the PDMS template polymer). In addition, a substantial fraction of the imprint cavities are localized at or near the surface of the matrix material (e.g., see figure 1 showing, top trace showing "all" of the cavities located at the top of the surface). Zhao et al. disclose "oriented" cavities (e.g., see figure 1 wherein the cavities are all perpendicularly oriented with the surface; see also specification, page 12, paragraph 1 wherein the term "oriented" is defined as having a "...a similar or identical spatial relationship to the surface of the matrix material").

Furthermore, it is submitted that the product of Zhao et al. meet all of the structural limitations of the claimed product (see above) except for the product-by-process limitations (i.e., the recited method steps for forming the cavities) and thus would either anticipate or render obvious the claimed library. See MPEP § 2113, "'[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." Here, Applicants' claims are drawn to a composition (i.e., a product), but are defined by various method

steps that produce said composition and, as a result, represent product-by-process claims. Thus, the process limitations do not appear to provide any patentable weight to the claimed invention in accordance with MPEP § 2113. One of ordinary skill would expect the product to be the same no matter how it was synthesized and/or prepared because the claim does not set forth what the conjugate molecule is contacted with (e.g., see 35 U.S.C. § 112, second paragraph). In addition, a medium (i.e., biphasic) is not set forth in the claimed process steps that might otherwise enable cavities formed from template-tail conjugates to be distinguished structurally from those formed from template molecules alone (e.g., see specification, section 5.3.1 wherein a "two-phase" system is required to impart "structural differences" using template-tail molecules). That is, unless a biphasic system is used in the process, a person of ordinary skill in the art would not expect a different cavity to be formed just because a "tail" has been added.

For ***claim 2 and 4***, Zhao et al. disclose photoresist polymers (e.g., see figure 1; see also page 1069, column 1, paragraph 2; see also 35 U.S.C. 112, second paragraph rejections above).

For ***claims 6-8***, Zhao et al. disclose a template molecule that corresponds to a portion of a macromolecule of interest (e.g., see figure 1, wherein the template corresponds to the terminal portions of the PDMS polymer that extend into the cavities).

13. Claims 1-8, 20, 23-25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Sobieszek (Sobieszek, A. "Gradient polyacrylamide gel electrophoresis in presence of sodium dodecyl sulfate: A practical

approach to muscle contractile regulatory proteins" *Electrophoresis* **1994**, *15*, 1014-10-20).

For ***claims 1 and 27***, Sobieszek discloses large and small gels (e.g., see abstract; see also sections 2.2-2.6), which anticipates the claimed invention. For example, Sobieszek discloses a surface imprint composition comprising a matrix material defining imprint cavities of a template molecule (e.g., see section 2.3-2.5). In this scenario, the acrylamide or polyacrylamide represents the matrix material that defines an imprint cavity from the template "comb" (i.e., defines the loading space at the top of each lane) and is made out of Teflon (e.g., see page 1015, column 1, section 2.3). Furthermore, the cavities (i.e., the wells at the top of each lane of the gel as defined by the comb) are located at the surface of the matrix material (i.e., the top of each lane). Sobieszek also discloses chambers that are oriented in a perpendicular direction with respect to the top of the gel (e.g., see sections 2.3-2.6; see also figures).

Furthermore, it is submitted that the product of Sobieszek et al. meet all of the structural limitations of the claimed product (see above) except for the product-by-process limitations (i.e., the recited method steps for forming the cavities) and thus would either anticipate or render obvious the claimed library. See MPEP § 2113, "'[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." Here, Applicants'

claims are drawn to a composition (i.e., a product), but are defined by various method steps that produce said composition and, as a result, represent product-by-process claims. Thus, the process limitations do not appear to provide any patentable weight to the claimed invention in accordance with MPEP § 2113. One of ordinary skill would expect the product to be the same no matter how it was synthesized and/or prepared because the claim does not set forth what the conjugate molecule is contacted with (e.g., see 35 U.S.C. § 112, second paragraph). In addition, a medium (i.e., biphasic) is not set forth in the claimed process steps that might otherwise enable cavities formed from template-tail conjugates to be distinguished structurally from those formed from template molecules alone (e.g., see specification, section 5.3.1 wherein a "two-phase" system is required to impart "structural differences" using template-tail molecules). That is, unless a biphasic system is used in the process, a person of ordinary skill in the art would not expect a different cavity to be formed just because a "tail" has been added.

For ***claims 2-5***, Sobieszek discloses acrylamide polymer including a heat sensitive hydrogel polyacrylamide (e.g., see abstract; see also sections 2.3-2.6).

For ***claim 6***, Sobieszek discloses a macromolecule of interest such as Teflon i.e., polytetrafluoroethylene (e.g., see section 2.3).

For ***claim 7***, Sobieszek discloses a comb, which is bond via non-covalent interactions at the imprint cavity (e.g., see sections 2.3-2.6).

For ***claim 8***, Sobieszek discloses binding to the terminal portions of the comb that extend into the wells of the matrix (e.g., see sections 2.3-2.6).

For ***claims 20 and 23-25***, Sobieszek discloses a plurality of surface imprint

compositions according to claim 1 (e.g., see sections 2.3 to 2.6 wherein both large and mini-gels are disclosed; see especially figure 3 wherein 28 minigels are simultaneously cast in a one/two dimensional array).

Response

14. To the extent that Applicants' arguments directed to the previous 35 U.S.C. § 102 rejections could be reiterated here against the 35 U.S.C. § 102/103 rejections, the following points are noted:

[1] Applicants argue that the above cited references do not teach the product by process limitation wherein a "tail" moiety is used to create the imprint cavities (e.g., see 7/18/07 Response, pages

[1] It is respectfully submitted that the new "process" limitations in the "product-by-process" claims do not impart any patentable weight to the claimed composition because it is unclear what process steps are being claimed (e.g., see 35 U.S.C. § 112, second paragraph rejection). Furthermore, the "fraction" of "oriented" cavities at the surface now reads on any process because any number of cavities that are oriented at the surface (including a minute quantity produced randomly) would read on the currently claimed invention.11-14).

[2] Applicants argue that the above cited references do not teach a "fraction" of oriented "cavities" at the "surface" (e.g., see 7/18/07 Response, pages 11 –14).

[2] The Examiner contends that this limitation reads on all matrix forming processes

because the number of "cavities" at the "surface" could be as little as one generated via a random process.

Accordingly, the 35 U.S.C. §§ 102/103 rejections cited above are hereby maintained.

Conclusion

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jon D. Epperson/
Primary Examiner, AU 1639